DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 21 1999

NDA 18-240/S-026
NDA 18-760/S-023
NDA 19-058/5-013

Zeneca Pharmaceuticals
Attention: W. J. Kennedy, Ph.D.
1800 Concord Pike
P.O. Box 15437
Wilmington, DE 19850-5437

Dear Dr. Kennedy:

Please refer to your supplemental new drug applications dated June 2, 1999, received June 3, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tenormin (atenolol) 25, 50 and 100 mg Tablets (18-240/S-026), Tenoretic (atenolol and chiorthalidone) 50/25 and 100/25 mg Tablets (18-760/S-023), and Tenormin (atenolol) 5 mg/l0 mL I.V. Injection Ampules (19-058/S-013).

We note that these supplements were submitted as 'Special Supplement - Changes Being Effected' under 21 CFR 314.70(c).

These supplemental new drug applications provide for final printed labeling revised as follows:

NDAs 18-240
18-760
19-058

The phrase, "dry mouth" has been added to the **ADVERSE REACTIONS** section, The address information has been changed to reflect a new logo.

NDAs 18-240
18-760

Under the **HOW SUPPLIED** section, the following sentence has been changed from:

Store at controlled room temperature, 15°-30° C (59°-86°F).

to:

Store at controlled room temperature, 20°-25° C (68°-77°F) [see USP].

NDA 19-058

Under the **HOW SUPPLIED** section, the following sentence has been changed from:

Store at room temperature.

to:

Store at controlled room temperature, 20°-25° C (68°-77°F) [see USP].

Your submission stated that these changes will be implemented during the first week of July 1999.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the final printed labeling included in your June 2, 1999 submission. Accordingly, these supplemental applications are approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Ms. Zelda McDonald
Regulatory Health Project Manager
(301) 594-5300

Sincerely,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research